

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
(SAN FRANCISCO DIVISION)

IN RE: VIAGRA (SILDENAFIL CITRATE)  
AND CIALIS (TADALAFIL) PRODUCTS  
LIABILITY LITIGATION

Case No.: 3:16-md-02691-RS  
MDL No. 2691

Judge Richard Seeborg

**Plaintiff(s)**

V.

PFIZER, INC., and ELI LILLY AND  
COMPANY

Defendant(s)

## **PLAINTIFFS' EXPERT DISCLOSURE ON GENERAL CAUSATION**

1. Sonal Singh M.D., M.P.H., Associate Professor of Medicine, Department of Family Medicine and Community Health and the Meyers Primary Care Institute, University of Massachusetts Medical School, Massachusetts

Areas of Testimony: Issues of epidemiology and statistics. Whether phosphodiesterase-5 (PDE-5) inhibitors, such as sildenafil, are causally related to the development of melanoma, melanoma epidemiology and risk factors, considerations of study design, methodology, pertinent medical literature. All issues of epidemiological general causation, including medical literature and analyses.

2. Rizwan Haq, M.D., Ph.D., Assistant Professor, Harvard Medical School, Dana Farber Cancer Institute, Associate Physician Brigham and Women's Hospital

Areas of Testimony: Biology of Melanoma. The biological mechanism of action underlying the increased risk of melanoma observed in peer-reviewed epidemiological studies where individuals used the PDE5 inhibitor sildenafil. All issues of general causation, including medical literature, mechanism of action, pre-clinical data, biological pathways, medical literature and analyses.

3. Susana Ortiz-Urda, M.D., Ph.D., Assistant Clinical Professor, Department of Dermatology, University of California, San Francisco

Areas of Testimony: The biological mechanism exists by which sildenafil causes increased growth and invasiveness of melanoma. All issues of general causation,

1 including medical literature, mechanism of action and all elements of general  
2 clinical and post-marketing data, medical literature and analyses.

3 4. Feng Lui-Simth, Ph.D., Assistant Professor, Department of Epidemiology, School of  
5 Medicine, University of California Irvine.

6 Areas of Testimony: Issues of epidemiology and biological mechanism of  
7 melanoma. The relationship between phosphodiesterase 5 (PDE5) inhibitors  
8 ("PDE5i") including sildenafil, vardenafil, avanafil, and tadalafil, and the  
9 increased the risk of melanoma development and/or increased the risk of growth  
10 and invasiveness of melanoma. All issues of general causation, including  
11 epidemiology, medical literature and mechanism of action as it relates to general  
12 causation.

13 5. Gary Piazza, Ph.D., Professor of Oncologic Sciences and Pharmacology, Chief of the  
14 Drug Discovery Research Center, and Director of Experimental Therapeutics and  
15 Chemoprevention, University of South Alabama, Mitchell Cancer Institute

16 Areas of Testimony: Pharmacologic properties of sildenafil and tadalafil,  
17 pharmacologic properties of sildenafil and tadalafil, whether sildenafil and/or  
18 tadalafil has clinically relevant anti-cancer activity in melanoma, whether the  
19 effect of sildenafil and/or tadalafil on the growth and invasiveness of melanoma is  
20 limited to the time the drug is present in the system, whether the effect of  
21 sildenafil and/or tadalafil on the growth and invasiveness of melanoma is limited  
22 to the time the drug is present in the system. All issues of general biological and  
23 mechanistic causation, including medical literature, pre-clinical and experimental  
24 data, medical literature and analyses.

25 6. Anand Krishnan Ganesan, M.D., Ph.D. Associate Professor, Department of  
26 Dermatology and Department of Biological Chemistry, University of California, Irvine

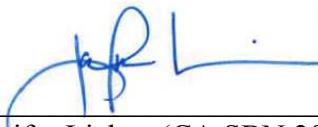
27 Areas of Testimony: Causative link and mechanism of action between use of  
28 PDE5-Is, including tadalafil, and the development and growth/invasiveness of  
29 melanoma. All issues of general biological mechanistic causation, including  
30 medical biological literature, mechanistic biological pathways of melanoma,  
31 medical literature and analyses.

32 7. Rehana L. Ahmed-Saucedo, M.D., PhD. Assistant Professor, Department of  
33 Dermatology, University of Minnesota

34 Areas of Testimony: The biological mechanism exists by which tadalafil causes  
35 increased growth and invasiveness of melanoma; the effects of PDE5-I exposure  
36 on human and mouse melanoma cells; mechanisms through which use of PDE5-Is  
37 could plausibly lead to the development of melanoma, both in vitro (cell culture)  
38 and in vivo (animal studies); and whether there is, in human populations, a true  
39 association between use of PDE5-Is and risk of subsequent development of  
40 melanoma. All issues of general causation, including medical literature,  
41 mechanism of action and all elements of general clinical and post-marketing data,  
42 medical literature and analyses.

1 Dated this the 20th day of April, 2017.

2 Respectfully submitted on behalf of the Plaintiff,

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4   
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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing was electronically filed through the Court's CM/ECF system on April 20, 2018, which shall send notification of such filing to all CM/ECF participants.

/s/ Veronica Maravilla